MAY 0 8 2002

K020723

Summary of Safety and Effectiveness Information

Dade Behring Dimension® ALDL Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

Submitter's Name:

Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: March 5, 2002

Name of Product: Dade Behring Dimension® ALDL Calibrator

FDA Classification Name: Calibrator, Secondary; Class II ; 75JIT

Predicate Device: The Dade Behring Dimension® AHDL Calibrator (K983850)

Device Description:

The Dade Behring Dimension® ALDL Calibrator is a 3 level, lyophilized product. The carton consists of six vials; two at each of three levels.

Lot specific Value Assignment is made according to the process outlined in ATTACHMENT C.

The Stability Testing Protocol established for determining long-term, real-time stability is provided in ATTACHMENT D. Shelf-life stability (Expiration Dating) dating reflects the real-time stability data available at commercialization and is on file at Dade Behring.

Intended Use:

The Dade Behring Dimension® ALDL Calibrator is an *in vitro* diagnostic product intended to be used to calibrate low density

lipoprotein cholesterol on Dade Behring Dimension® clinical chemistry systems.

Comparison to Predicate Device:

Feature	Dimension® ALDL Calibrator	Dimension® AHDL Calibrator
Intended Use:	*In vitro* use. For calibration of human low density lipoprotein cholesterol on Dimension® systems	*In vitro* use. For calibration of human high density lipoprotein cholesterol on Dimension® systems
Levels:	3 levels; two vials/level	3 levels; two vials/level
Form:	Lyophilized	Liquid
Matrix:	bovine serum albumin with added human LDL	bovine serum albumin with added human HDL

Comments on Substantial Equivalence:

The proposed Dade Behring Dimension® ALDL Calibrator and the predicate Dade Behring AHDL Calibrator are similar *in vitro* diagnostic products. Both are intended be used as cholesterol calibrators for the Dade Behring Dimension® clinical chemistry system analyzer family.

Conclusion:

The Dade Behring Dimension® ALDL Calibrator is substantially equivalent to other lipoprotein calibrators such as the Dade Behring Dimension® AHDL Calibrator based on its design and function as summarized above.

Richard M. Vaught
Regulatory Affairs and Compliance Manager
March 5, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
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MAY 0 8 2002

Re: k020723
Trade/Device Name: Dade Behring Dimension® ALDL Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, secondary
Regulatory Class: Class II
Product Code: JIT
Dated: March 5, 2002
Received: March 6, 2002

Dear Mr. Vaught:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name:

Dade Behring Dimension® ALDL Calibrator

Indications for Use:

The Dade Behring Dimension® ALDL Calibrator is an *in vitro* diagnostic device intended for use on Dade Behring Dimension® clinical chemistry systems for medical purposes to establish points of reference that are used in determination of low density lipoprotein cholesterol in human serum and plasma

Richard M. Vaught
Regulatory Affairs and Compliance Manager

March 5, 2002

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020723

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)